JUN 13 2012

CardinalHealth

1430 Waukegan Road
McGraw Park, IL 60085

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SMDA REQUIREMENTS K120658

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

DuraBlue™ Sterilization Wrap

Manufacturer:	Cardinal Health 200, LLC 1430 Waukegan Road McGaw Park, IL 60085
Regulatory Affairs Contact:	Lavenia Ford 1430 Waukegan Road McGaw Park, IL 60085
Telephone Number:	(847) 887-3323
Date summary Prepared:	May 31, 2012
Trade Name:	DuraBlue™ Sterilization Wrap
Classification:	Class II per 21 CFR § 880.6850
Classification Name:	Sterilization Wrap
Predicate Devices:	K112211 – DuraBlue™ Sterilization Wrap – Pre-Vacuum Steam (4 min/270°) K112283 - DuraBlue™ Sterilization Wrap – STERRAD 100S K112918 - DuraBlue™ Sterilization Wrap - Amsco® V-PRO™ 1 & 1 Plus (Lumen & Non Lumen Cycles) and Amsco® V-PRO™ maX (Flexible Cycle)

Description:

Cardinal Health DuraBlue™ Sterilization Wraps are double layer sterilization wraps made from 100% polypropylene spunbond-meltblown-spunbond (SMS) fabric. They are intended to be used to enclose another medical device that is to be sterilized by a health care provider by pre-vacuum steam at 270°F/132°C for 4 minutes, STERRAD® 100S System and the Lumen, Non Lumen, or Flexible Cycles in the Amsco® V-PRO™ 1, Amsco® V-PRO™ 1 Plus and Amsco® V-PRO™ MAX Low Temperature Sterilization Systems. This wrap design allows for use of the simultaneous double-wrapping technique and also allows for a sterilized pack to be opened aseptically.

The only modification to the predicate devices is the clarification to the sterility maintenance information provided in the Indication for Use portion of the Instructions for Use labeling:

- Predicate Statement:

  "The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) for 30 days."

- Proposed Statement:

  "The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s). Maintenance of package sterility was validated with real-time testing for the following durations:

  - 180 days following sterilization by STERRAD 100S and Amsco® V-PRO™ (Lumen, Non Lumen, and Flexible Cycles).
  - 30 days following sterilization by pre-vacuum steam at 270°F/132°C for 4 minutes."

This modification is based on Event-Related Shelf Life testing that demonstrates that the DuraBlue™ wrap maintains sterility of the enclosed contents for the 180 day test period following sterilization by STERRAD 100S or Amsco® V-PRO™ (Lumen, Non Lumen, and Flexible Cycles).

Extensive performance testing has also been completed on Cardinal Health DuraBlue™ Sterilization Wrap in the predicate Premarket Notifications. Successful completion of the sterilization performance tests demonstrated that the wrap allows for sterilization of the enclosed contents. Physical Properties testing included in the predicate Premarket Notifications also supports the fact that the integrity of the wrap properties is not compromised after sterilization by the indicated modalities and storage because the polypropylene material is inert and very stable. The data is included in each of the cleared Premarket Notifications, K112211, K112283, and K112918.

This submission covers six different models of Cardinal Health DuraBlue™ Sterilization Wrap. Each model is made from material of a different basis weight, though all models utilize the same material technology.

Indications for Use

Cardinal Health DuraBlue™ Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider by the following modalities:

- Pre-vacuum steam at 270°F/132°C for 4 minutes
- STERRAD® 100S system.
- Lumen, Non Lumen, and Flexible Cycles in the Amsco® V-PRO™ 1, Amsco® V-PRO™ 1 Plus and Amsco® V-PRO™ maX Low Temperature Sterilization Systems

The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s). Maintenance of package sterility was validated with real-time testing for the following durations:

- 180 days following sterilization by STERRAD 100S and Amsco® V-PRO™ (Lumen, Non Lumen, and Flexible Cycles).
- 30 days following sterilization by pre-vacuum steam at 270°F/132°C for 4 minutes.

Cardinal Health DuraBlue™ Sterilization Wrap is not indicated for use with gravity steam sterilization.

For pre-vacuum steam sterilization, the wrap has been validated for dry times of 20 minutes for Models CH100 and CH200, and for 30 minutes for Models CH300, CH400, CH500 and CH600. Models CH400, CH500 and CH600 have been validated for pre-vacuum steam sterilization of lumens 3 mm in diameter or larger and 400 mm in length or less. All models have been validated for STERRAD® 100S sterilization of lumens 2.5 mm in diameter or larger and 250 mm in length or less.

All models of DuraBlue™ Sterilization Wrap have been validated for use with the following Amsco® V-PRO™ cycles. The DuraBlue™ Sterilization Wrap was validated to be effectively aerated during the pre-programmed Amsco® V-PRO® sterilization cycles.

Validated Amsco® V-PRO™ cycles

Amsco® V-PRO® Cycle	Maximum Recommended Chamber Load	Intended Load
Lumen Cycle	19.65 lbs	Reusable metal and non-metal medical devices, including up to 20 lumens of the following dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 125 mm or shorter • an inside diameter of 2 mm or larger and a length of 250 mm or shorter • an inside diameter of 3 mm or larger and a length of 400 mm or shorter
Non Lumen Cycle	19.65 lbs	Non-lumened reusable metal and non-metal medical devices
Flexible Cycle	24 lbs	Single or dual lumen surgical flexible endoscopes and bronchoscopes in either of two load configurations: 1. Two trays, each containing a flexible endoscope with a light cord (if not integral to endoscope) and mat with no additional load 2. One tray containing a flexible endoscope with a light cord (if not integral to endoscope) and mat and an additional tray containing non-lumened medical devices The flexible endoscope(s) may contain either: • a single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter • two lumens, with one lumen having an inside diameter of 1 mm or larger and a length of 998 mm or shorter and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter

Wrap Model Recommendations for Pre-Vacuum Steam Sterilization

Sterilization Wrap Model	Intended Load	Maximum Recommended Wrapped Package Content Weights[2]
CH100	Very light weight package (for example: towel packs).	3 lbs (1,36 kg)
CH200	Light weight package (for example: standard linen packs).	6 lbs (2,7 kg)
CH300	Light to moderate weight package (for example: general use medical instruments).	9 lbs (4 kg)
CH400	Moderate to heavy weight package (for example: general use medical instruments).	13 lbs (5,9 kg)
CH500	Heavy weight package (for example: general use medical instruments).	17 lbs (7,7 kg)
CH600	Very heavy weight package (for example: general use medical instruments).	25 lbs (11,3 kg)

Wrap Model Recommendations for STERRAD® 100S Sterilization and V-PRO™ Sterilization

Sterilization Wrap Model	Intended Load	Maximum Recommended Wrapped Package Content Weights[2]	
		STERRAD® 100S	V-PRO™
CH100	Very light weight package (for example: batteries).	3 lbs (1.36 kg)	3 lbs
CH200	Light weight package (for example: telescope with light cord).	6 lbs (2.7 kg)	6.5 lbs
CH300	Light to moderate weight package (for example: general use medical instruments).	10 lbs (4.4 kg)	9 lbs
CH400	Moderate to heavy weight package (for example: general use medical instruments).	10 lbs (4.4 kg)	9.1 lbs
CH500	Heavy weight package (for example: general use medical instruments).	10 lbs (4.4 kg)	9.1 lbs
CH600	Very heavy weight package (for example: general use medical instruments).	10 lbs (4.4 kg)	9.1 lbs

Substantial Equivalence

The proposed DuraBlue™ Sterilization Wrap is substantially equivalent to the predicate devices. Both devices:

- Have the same intended use
- Have the same material composition
- Have the same physical and chemical properties
- Have the same configurations/dimensions
- Are indicated for the same sterilization parameters
- Are indicated for the same Maximum Wrapped Package Content Weights

Summary of Testing

DuraBlue™ Sterilization Wrap performance has been tested in accordance with the applicable requirements recommended in the FDA's Guidance Document Premarket Notification 510(k) Submissions for Medical Sterilization Packaging System in Health Care Facilities; Draft Guidance for Industry and FDA (March 7, 2002) in the predicate Premarket Notifications. Risk analysis showed that the modification to the information provided in the labeling does not present an increase or change in risk of illness or injury associated with the use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 13 2012

Ms. Lavenia Ford
Manager, Regulatory Affairs
Cardinal Health 200, LLC
1430 Waukegan Road
McGaw Park, Illinois 60085

Re: K120658
Trade/Device Name: Cardinal Health DuraBlue™ Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: June 1, 2012
Received: June 4, 2012

Dear Ms. Ford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

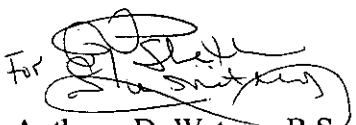
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, ~~B.S.,~~ M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CardinalHealth

Indications for Use Form

510(k) Number (if known): K120658

Device Name: Cardinal Health DuraBlue™ Sterilization Wrap

Indications for Use

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Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Devices Evaluation (ODE)

Elizabeth F. Claus-Wilson

Division Sign-Off
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) K120658

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: _____

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